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IP

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/461,709 12/14/99 BARCLAY

W 2997-1-3-2

HM22/0409

[REDACTED] EXAMINER

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ART UNIT	PAPER NUMBER
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1651

b

DATE MAILED:

04/09/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)
	09/461,709	Barclay
	Examiner Ware	Group Art Unit 1651
<i>—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—</i>		
Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>— 3 —</u> MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.		
<ul style="list-style-type: none"> - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication . - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). 		
Status		
<input checked="" type="checkbox"/> Responsive to communication(s) filed on <u>3/19/01</u>		
<input type="checkbox"/> This action is FINAL.		
<input type="checkbox"/> Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11; 453 O.G. 213.		
Disposition of Claims		
<input checked="" type="checkbox"/> Claim(s) <u>38-93</u> is/are pending in the application.		
Of the above claim(s) <u>38-52 & 67-93</u> is/are withdrawn from consideration.		
<input type="checkbox"/> Claim(s) _____ is/are allowed.		
<input checked="" type="checkbox"/> Claim(s) <u>53-66</u> is/are rejected.		
<input type="checkbox"/> Claim(s) _____ is/are objected to.		
<input type="checkbox"/> Claim(s) _____ are subject to restriction or election requirement.		
Application Papers		
<input type="checkbox"/> See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.		
<input type="checkbox"/> The proposed drawing correction, filed on _____ is <input type="checkbox"/> approved <input type="checkbox"/> disapproved.		
<input type="checkbox"/> The drawing(s) filed on _____ is/are objected to by the Examiner.		
<input type="checkbox"/> The specification is objected to by the Examiner.		
<input type="checkbox"/> The oath or declaration is objected to by the Examiner.		
Priority under 35 U.S.C. § 119 (a)-(d)		
<input type="checkbox"/> Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).		
<input type="checkbox"/> All <input type="checkbox"/> Some* <input type="checkbox"/> None of the CERTIFIED copies of the priority documents have been		
<input type="checkbox"/> received.		
<input type="checkbox"/> received in Application No. (Series Code/Serial Number) _____.		
<input type="checkbox"/> received in this national stage application from the International Bureau (PCT Rule 17.2(a)).		
*Certified copies not received: _____.		
Attachment(s)		
<input type="checkbox"/> Information Disclosure Statement(s), PTO-1449, Paper No(s). _____ <input type="checkbox"/> Interview Summary, PTO-413		
<input type="checkbox"/> Notice of Reference(s) Cited, PTO-892 <input type="checkbox"/> Notice of Informal Patent Application, PTO-152		
<input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review, PTO-948 <input type="checkbox"/> Other _____		
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Claims 38-93 are pending in the instant application.

1. Applicant's election with traverse of Group II, claims 53-66, in Paper No. 5 is acknowledged. The traversal is on the ground(s) that there is no burden presented to the examiner to search all distinct and independent invention(s). This is not found persuasive because two way distinctness may be found between each of the method claims and one way distinctness between each of methods and product claims. Wherein different conditions and process steps are required for the methods. However, the restriction requirement between the products is removed. Although one of the products depends from the process of claim 53, the process as claimed may be useful for making a different product and the product may be made by a different process. However, if during the search for the process encompassed by claims 53-66 art which may read on the product claims is discovered without a serious burden then such art may be applied to the product claims and the restriction between method claims 53-66 and the product claims will be removed and those claims examined together. Also if the art searched for claims 53-66 during prosecution turns up art which may read on other claims pending in the instant case then the restriction requirement will be removed accordingly. Also claims may be rejoined at any time during the prosecution if it is deemed that all pertinent art has been found and searched; and further this same fact is true at time of allowance, if all claims are deemed allowable and adequately searched. However, at this time Applicant's argument is not deemed persuasive and only claims 53-66 will be searched. Thus, the requirement is still deemed proper but has not necessarily been made final at this time.

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2. Claims 38-52 and 67-93 are withdrawn from further consideration pursuant to 37 CAR 1.142(b), as being drawn to a nonelected invention(s), there being no allowable generic or linking claim determined at this time. Applicant timely traversed the restriction (election) requirement in Paper No. 5.

3. Claims 53-66 will be examined on the merits. The Information Disclosure Statement (IDS) filed January 31, 2000, has been received. However, the references although they have been reviewed are not indicated as such on the IDS in the file since the form is incomplete with respect to a listing of the classes and subclasses. Thus, it is requested that applicants file a copy with the classes and subclasses filled in, accordingly, in order that the form may be complete upon Applicant's submission of such copy. Further, note that this is merely a complete copy being requested and that no fee or certification is necessary since the IDS was officially filed before the first office action was mailed.

4. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 58 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

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Since the microorganism is required and recited in the claims it is essential to the whole invention as recited in those claims. It must therefore be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the microorganism is not so obtainable or available, the requirements of 35 U.S.C. § 112 may be satisfied by a deposit of the microorganism. The specification does not disclose a repeatable process to obtain the microorganism and it is not apparent if the microorganism is readily available to the public. It is noted that applicants have deposited the organism but there is no indication in the specification as to public availability.

If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain will be irrevocably and without restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. §§ 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

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- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer; and
- (d) the deposit will be replaced if it should ever become inviable.

Applicant is directed to 37 CAR § 1.807(b) which states:

- (b) A viability statement for each deposit of a biological material defined in paragraph (a) of this section not made under the Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure must be filed in the application and must contain:
 - (1) The name and address of the depository;
 - (2) The name and address of the depositor;
 - (3) The date of deposit;
 - (4) The identity of the deposit and the accession number given by the depository;
 - (5) The date of the viability test;
 - (6) The procedures used to obtain a sample if the test is not done by the depository; and
 - (7) A statement that the deposit is capable of reproduction.

Applicant is also directed to 37 CAR § 1.809(d) which states:

- (d) For each deposit made pursuant to these regulations, the specification shall contain:
 - (1) The accession number for the deposit;
 - (2) The date of the deposit;
 - (3) A description of the deposited biological material sufficient to specifically identify it and to permit examination; and
 - (4) The name and address of the depository.

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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6. Claims 53-66 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 53-66 are rendered vague and indefinite for the recitation of unclear process steps. The process step of extracting lipids from euryhaline microorganisms is unclear since it requires the extraction from the microorganisms and not the fermentation medium. Thus, it is unclear as to whether the product is being produced within the microorganism or within the fermentation medium. The metes and bounds of the claims are uncertain. Further, the recitation of "the microorganism" in the dependent claims lacks antecedent basis since the process requires more than one microorganism. Thus, it is suggested to pluralize the term "microorganism" in the dependent claims wherein such change is warranted and would appear to make the claim clear and definite, accordingly.

7. Claims 53-56 and 59-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a euryhaline microorganism of the genus *Thraustochytrium*, *Schizochytrium* and mixtures thereof, the specification does not reasonably provide enablement for any and all euryhaline microorganisms for use in the claimed method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to carry out the process steps of the invention with any other genus of euryhaline microorganism. Therefore, the enablement of the claimed invention is not commensurate in scope with the claimed subject matter.

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No claims are allowed.

The claims appear to be free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah K. Ware whose telephone number is (703) 308-4245. The examiner can normally be reached on Mondays to Fridays from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Wityshyn, can be reached on (703) 308-4743. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3592.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


DEBORAH K. WARE
PATENT EXAMINER

Deborah K. Ware

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April 2, 2001